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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,320	06/12/2001	Ajay Hasmukhlal Upadhyay	RD 01022	5176

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,320

Applicant(s)

UPADHYAY, AJAY HASMUKHLA

Examiner

Lakshmi S Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 11-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

Art Unit: 1615

DETAILED ACTION

Receipt of response to restriction requirement, dated 10-7-02 is acknowledged.

Election/Restrictions

Applicant's election without traverse of group I, claims 1-10, in Paper No. 5 is acknowledged.

Status of Claims

Claims 1-10 have been elected and presented for examination. Claims 11-20 are withdrawn from consideration as being non-elected.

Instant claim 1 is directed to a composition comprising guaifenesin and a binder and being in the form of particles, wherein less than about 30% by weight of the particles are greater than 425 micrometers in size and greater than about 80% by weight of particles are greater than about 45 micrometers. Dependent claims 2 and 3 require the presence of solubilizer, glidants and lubricant, in addition to guaifenesin and binder. Dependent claims 4-6, 9 and 10 recite specific amounts of guaifenesin and the other excipients of claims 2-3. Claim 8 recites a specific flow rate.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1615

The recitation of particle sizes in terms of percentages in the instant claims is vague and confusing because in claim 1, from the limitation “less than about 30% by weight of the particles exhibit a particle size of greater than about 425 micrometer” it appears that the particles in the size range of greater than 425 microns is not essential for the composition. Less than 30% includes 0%. Similarly, from the limitation “greater than about 80% by weight of the particles exhibit a particle size of greater than about 45 micrometer” includes any size above 45 microns i.e., even 425 microns. It is unclear from the claim expression as what particle sizes are being claimed by applicants. A clarification and correction is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US 4,711,774 to Denick, Jr. et al (Denick).

Instant claim 1 is directed to a composition comprising guaifenesin and a binder and being in the form of particles, wherein less than about 30% by weight of the particles are greater than 425 micrometers in size and greater than about 80% by weight of particles are greater than about 45 micrometers. See above 112, 2nd paragraph rejection with respect to particle sizes claimed.

Art Unit: 1615

Denick discloses compositions containing guaifenesin mixed with magnesium aluminum silicate until a homogenous mixture is obtained (see example 1, in col. 11, lines 20-43).

Magnesium aluminum silicate is used as an adsorbate for guaifenesin. Although Denick does not call it binder, it reads on instant binder because the term is broad and does not define any specific compound. Further, Denick discloses that the composition is dried and milled to produce a free flowing particulate material having a particle size of about 100 microns. Instant claim states less than 30% particles have a size greater than 425 microns, which includes 0%-30%. In other words, particles >425 microns are not required for the composition. Accordingly, the composition of Denick anticipates instant composition of claim 1.

Claim Rejections - 35 USC § 103

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over 4,711,774 to Denick, Jr. et al (Denick).

Denick, discussed above, teaches a particulate composition comprising guaifenesin and magnesium aluminum silicate. Denick teaches that the particle size of the composition, upon milling to a free flowing composition, is about 100 microns (example 1). Further, Denick suggests that the particulate size ranging from 10 to 150 microns is suitable for the invention i.e., to prepare a guaifenesin composition containing magnesium aluminum silicate as an adsorbate. As explained above, instant claims do not specify any binder and accordingly, magnesium aluminum silicate of Denick reads on instant binder. Denick differs from the instant claims in the percentages of particle sizes. Instant Claim 5 requires 10-60 percent particles in the range of 45 to 150 microns; claim 6 requires > 10% particles having > 75 microns and > 55% particles having 45 microns; claim 7 requires < 25% exhibit a size range greater than 425 microns, 17%-

Art Unit: 1615

55% particles are in a range of 45-150 microns and > 85% particles have > greater than 45 microns. It would be obvious for one of ordinary skill in the art at the time of the instant invention to choose and obtain guaifenesin composition having claimed particle sizes because Denick teaches that suitable particle sizes in the range of 10-150 microns are preferred for adsorbing sufficient quantities of medicament solution to prepare an acceptable drug product.

Denick does not state the flow rate recited in claim 8. However, it is the position of the examiner that because Denick teaches particles in the same size range as required by the claims, optimizing the flow rate to produce a free flowing particulate formulation, having the claimed flow rate would have been obvious for a skilled artisan at the time of the instant invention.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,372,252 to Blume et al (hereafter Blume).

Blume teaches sustained release formulations comprising guaifenesin, a hydrophilic polymer such as hydroxypropyl methylcellulose, a water insoluble polymer and other tableting ingredients (col. 4, lines 4-28 and col. 6, lines 1-43). Among the pharmaceutical additives, Blume teaches lubricants such as magnesium stearate, calcium stearate etc; binders such as povidone (polyvinylpyrrolidone), gelatin, starch; glidants such as talc or silicon dioxide, stabilizers and other excipients such as lactose, sorbitol etc (col. 6, lines 45-65). Further, Blume teaches preparing the composition by granulation and compression (col. 8), which includes as one of the steps, drying and milling the composition and passing through sieves of 100 mesh screen size (col. 8, lines 20-25). Examiner notes that a 100-mesh size screen allows for particles of 150-micron size (see instant description on page 14). Accordingly, Blume suggests preparing particles in the similar size ranges as that of the instant invention. Blume does not teach the exact

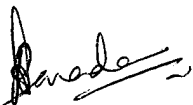
Art Unit: 1615

percentages of the particle sizes as claimed. However, optimizing the particle sizes of guaifenesin comprising medicament formulation depending on the type of preparation i.e., compression tablet (col. 8) or a capsule (col. 9) would have been obvious for one of an ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala
Examiner
Art Unit 1615
November 16, 2002